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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,935	05/03/2001	David F. Woodward	D2914	6555

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/847,935

**Applicant(s)**

WOODWARD ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36,37,39-41,43-50,53-66,68 and 70-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60-66,68 and 72-77 is/are allowed.
- 6) ☒ Claim(s) 36, 45, 46 and 78-86 is/are rejected.
- 7) ☒ Claim(s) 37,39-41,43,44,47-50,53-58,70 and 71 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1615

### **DETAILED ACTION**

Examiner acknowledges receipt of remarks filed 08/24/04. Claims 36, 37, 39-41, 43-50, 53-66, 68, 70-86 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 59, 78-80 and 83-86 remain rejected under 35 U.S.C. 102(e) as being anticipated by Garst (US 6,294,563).
2. Claims 78-86 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gil et al. (US 6,294,553).

Applicants state: "claim 59 is directed to a composition that comprises an adrenergic agonist and an efficacy enhancing component provided in an amount that is effective to form an ion-pair complex with the adrenergic agonist which remains substantially intact in a high dielectric constant solvent." Applicants further state: "claim 78 and the claims dependent therefrom, are directed to a liquid composition comprising a therapeutic component and an efficacy enhancing component provided in an amount effective to form a complex, which is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component."

Applicants argue that neither Garst nor Gil discloses, suggests or anticipates the claimed compositions in claims 59 and 78 and subsequently the claims that depend from these claims because neither Garst nor Gil expressly or inherently disclose compositions that comprise efficacy enhancing component provided in amounts recited in the claims and thus, while Garst and Gil disclose or encompass aspects of the present invention, Garst or Gil does not teach each

Art Unit: 1615

and every limitation recited in the instant claims. Therefore, if Examiner maintains the rejections, applicants request the “Examiner to specifically identify where Garst and Gil expressly or inherently disclose the claimed compositions” or provide other evidence in the prior art to support the Examiner’s opinion that the complexes of the present claims would necessarily be formed in the prior art” and applicants further request the Examiner to provide a reference “with support from an affidavit showing that ion-pair complexes, or complexes as recited in claim 78, necessarily form when mixing pharmaceutical components,” and that “absent such a showing,” applicants state that the “rejections cannot be maintained, and must be withdrawn.”

***Response to Arguments***

3. Applicants' arguments filed 08/24/04 have been fully considered but they are not persuasive.

Claims 59 and 78 are directed to a composition that comprises an adrenergic agonist and an efficacy-enhancing component. Claim 78 is a liquid and claim 59 does not indicate liquid or solid. Garst and Gil disclose compositions that contain therapeutic component and efficacy enhancing component. The claim language uses “comprising,” which implicates the composition to have other components besides the therapeutic component. Examined composition comprises therapeutic component and efficacy enhancing component just as the compositions of the prior art. Examined claims then recite “efficacy enhancing component provided in an amount effective to form an ion-pair complex with the adrenergic agonist which remains substantially intact in a high dielectric constant solvent,” or “efficacy enhancing component provided in an amount effective” to form a complex, which is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical

Art Unit: 1615

composition “in which the therapeutic component is not complexed with the efficacy enhancing component.” Now, there are two compositions that are essentially the same, one is the claimed composition and the other is the composition of the prior art. Without knowing possible differences between both compositions or without being presented with differences between the composition by the instant claims, it is appropriate to state that what the instant composition does, the prior art composition will also do; the property of the instant composition will also be the property of the prior art composition and the future intended use(s) of compositions is not critical in composition claims. In response to applicants’ remarks of 02/17/04, Examiner presented Examiners position that the property of a composition is inherent to the composition and the property of the composition cannot be separated from composition. The question is, why would an efficacy enhancing component A, say, in **one** composition comprising therapeutic component B, say, and efficacy enhancing component A form a complex with the therapeutic component B and an efficacy enhancing component A in **another** composition comprising therapeutic component B and an efficacy enhancing component A not form a complex with the therapeutic component B? The scope of the claims is broad and reads on the prior art.

“An amount effective to form...” is an amount effective to form... and any amount reads on this broad amount. Applicants are requiring Examiner to either cite prior art or provide affidavit to show that ion-pair complex would form in a prior art composition that comprises A and B just as the instant composition comprising A and B forms ion-pair complexes. However, the burden is on applicants to demonstrate what sets the compositions apart and a showing or affidavit from the Examiner is not given because the instant composition comprising A and B reads on the prior art composition that comprises A and B. Applicants have not provided the

Art Unit: 1615

differences between the instant composition and the prior art composition that affords the distinction between the compositions.

***Claim Rejections - 35 USC § 103***

4. The rejection of claims 36, 37, 39-41, 43, 44, 47-50, 53-58, 70-75 and 77 under 35 U.S.C. 103(a) as being unpatentable over Garst (US 6,294,563) is withdrawn because applicants provided a statement that both the application and Garst were at the time of the invention commonly assigned, which removes Garst as art under 35 USC 103.

5. The rejection of claims 60-66, 68, 72, 73 and 76 under 35 U.S.C. 103(a) as being unpatentable over Gil et al. (US 6,294,553) is withdrawn because applicants provided a statement that both the application and Gil were at the time of the invention commonly assigned, which removes Gil as art under 35 USC 103.

Because the rejections over Garst and Gil are withdrawn, applicants' remarks on page 7 of the response filed 08/24/04 are moot. However, if the art prior art were retained, then it would show that the claimed invention as a whole is rendered obvious by Garst or Gil because differences in concentration will not support patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

6. Claims 36, 45 and 46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua et al. (US 5,795,909).

Applicants argue that Shashoua discloses about 8,000 compounds and that the listing of one agent among thousands of potential agents provides "nothing more than speculation of potential agent that can be provided in a composition," and that based on Shashoua, a person of

Art Unit: 1615

ordinary skill in the art would guess, test and pick and chose brimonidine tartrate from the long list of agent.

***Response to Arguments***

7. Applicants' arguments filed 08/24/04 have been fully considered but they are not persuasive.
8. The response to the issue of complex formation is the same as presented for Garst and Gil. Applicants admit that Shashoua discloses brimonidine tartrate and although, this disclosure is among a list of other drugs, there is a disclosure and more that one adrenergic is disclosed and the adrenergics are a category of pharmaceuticals that can be formulated with the carrier/excipient of Shashoua. The rejection is not one of anticipation and a single reference may be sufficient to render obvious claims, see MPEP 706.02(j).
9. The withdrawal of Garst and Gil as prior art under 35 USC 103 leaves claims 37, 39-41, 43, 44, 47-50, 53-58, 70 and 71 as being objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. Claims 60-66, 68 and 72-77 are allowable because the prior art does not disclose ion pair complex that includes adrenergic agonist and efficacy enhancing component.
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after


Art Unit: 1615

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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